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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,235

11/20/2006

Laura Serino

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08/27/2009

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY- X100B

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

08/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/561,235		SERINO ET AL.	
	Examiner		Art Unit	
	S. Devi, Ph.D.		1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Lack of Unity

- 1) Claims 1-14 are under prosecution.
- 2) As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (“requirement of unity of invention”). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

- 3) As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
 - (1) A product and a process specially adapted for the manufacture of said product; or
 - (2) A product and process of use of said product; or
 - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
 - (4) A process and an apparatus or means specifically designed for carrying out the said process; or
 - (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

- 4) Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 C.F.R. 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-7, drawn to a composition comprising two or more of the gonococcal OmpA, OmpH, PPIase, ngs41, ngs117 and App.
- II. Claim 8, drawn to a hybrid polypeptide of the formula $\text{NH}_2\text{-A-}\{-\text{X-L-}\}_n\text{-B-COOH}$, wherein each X is an amino acid sequence derived from gonococcal OmpA, OmpH, PPIase, ngs41, ngs117 or App.
- III. Claim 9, drawn to a nucleic acid encoding the hybrid polypeptide of the formula $\text{NH}_2\text{-A-}\{-\text{X-L-}\}_n\text{-B-COOH}$, wherein each X is an amino acid sequence derived from gonococcal OmpA, OmpH, PPIase, ngs41, ngs117 or App.
- IV. Claim 10, drawn to a lipidated gonococcal OmpA protein.
- V. Claim 11 and 13, drawn to a lipidated gonococcal PPIase and dimeric gonococcal PPIase.
- VI. Claim 12, drawn to a dimeric gonococcal OmpH protein.
- VII. Claim 14, drawn to a gonococcal strain with one or more of the gonococcal OmpA, OmpH, PPIase, ngs41, ngs117 and App antigens knocked out.

5) Inventions I-VII lack unity. The special technical features of inventions I-VII are delineated above. The mixture of antigens of invention I, the hybrid polypeptide of invention II, and the diverse lipidated proteins of inventions IV-VI represent diverse products comprising amino acid residues. The nucleic acid of invention III comprises purine and pyrimidine units. The gonococcal strain of invention VII carries numerous antigenically divergent protein, polysaccharide and lipid antigens. These products or product combinations do not share significant structural elements. Furthermore, these products require separate and non-coextensive structural searches.

6) This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, the species lack the same or corresponding special technical features as these species do not share a *significant* common structure, function and/or antigenic make-up.

(I) Two or more gonococcal antigen combination species of invention I comprising OmpA, OmpH, PPIase, ngs41, ngs117 and App. See claims 1-7.

(II) The hybrid polypeptide species of invention II comprising an amino acid sequence from (a) SEQ ID NO: 2; (b) SEQ ID NO: 3; (c) SEQ ID NO: 4; (d) SEQ ID NO: 5; (e) SEQ ID NO: 6; and (f) SEQ ID NO: 7. See claim 8.

(III) The nucleic acid species of invention III encoding a hybrid polypeptide comprising an amino acid sequence from (A) SEQ ID NO: 2; (B) SEQ ID NO: 3; (C) SEQ ID NO: 4; (D) SEQ ID NO: 5; (E) SEQ ID NO: 6; and (F) SEQ ID NO: 7. See claim 9.

(IV) One or more knocked-out gonococcal antigen species of invention VII comprising OmpA, OmpH, PPIase, ngs41, ngs117 and App. See claim 14.

7) Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. If invention I is elected, Applicants should elect one bivalent, trivalent, tetravalent, pentavalent, or hexavalent antigen combination species. If invention VII is elected, Applicants should elect monovalent, bivalent, trivalent, tetravalent, pentavalent, or hexavalent knocked-out gonococcal antigen species.

Applicants are advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

8) The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record, showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C § 103(a) of the other invention.

9) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

10) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

August, 2009